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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,479	10/12/2001	Richard Boyd	156857-0034	2693

29000 7590 07/28/2003

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EXAMINER

BELYAVSKIY, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/28/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,479

Applicant(s)

BOYD, RICHARD

Examiner

Michail A Belyaevskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 15-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 15-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicant's amendment, filed 05/19/03 (Paper No: 9), is acknowledged.

Claims 15-54 are pending.

2. Applicant's election of Group II, claims 1-9 and 11-14, (now claims 15-54) in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In view of Applicant's Amendment filed 05/19/03 (Paper No: 9), the new Restriction Requirement is set forth below.

Restriction Requirement

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 15-23 , 25, 36 and 44-53 drawn to a method for improving a patient's immune response, wherein the patient has or had a disease, and wherein disruption of sex steroid mediated signaling is accomplished through inhibition of sex steroid production in the patient, classified in Class 424, subclasses 184.1.
 - II. Claims 15-23 , 26, 36 and 44-53 drawn to a method for improving a patient's immune response, wherein the patient has or had a disease, and wherein disruption of sex steroid mediated signaling is accomplished through blocking of one or more sex steroid receptors within the patient's thymus, classified in Class 424, subclasses 184.1.
 - III. Claims 15-23 and 27 -53 drawn to a method for improving a patient's immune response, wherein the patient has or had a disease, and wherein disruption of sex steroid mediated signaling is accomplished through administration of one or more pharmaceuticals that can lower the concentration of sex steroids in a patient, classified in Class 424, subclasses 184.1.

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- IV. Claims 15- 25, 36 and 44-53 drawn to a method for improving a patient's immune response, wherein the patient has or had a treatment of a disease, that at least in part deactivated the patient's thymus and wherein disruption of sex steroid mediated signaling is accomplished through inhibition of sex steroid production in the patient, classified in Class 424, subclasses 184.1.
- V. Claims 15- 25 , 26, 36 and 44-53 drawn to a method for improving a patient's immune response, wherein the patient has or had a treatment of a disease, that at least in part deactivated the patient's thymus and wherein disruption of sex steroid mediated signaling is accomplished through blocking of one or more sex steroid receptors within the patient's thymus , classified in Class 424, subclasses 184.1.
- VI. Claims 15- 25 and 27-53 drawn to a method for improving a patient's immune response, wherein the patient has or had a treatment of a disease, that at least in part deactivated the patient's thymus and wherein disruption of sex steroid mediated signaling is accomplished through administration of one or more pharmaceuticals that can lower the concentration of sex steroids in a patient , classified in Class 424, subclasses 184.1.
- VII. Claim 54, drawn to a kit for use in improving a patient's immune response, classified in Class 435, subclass 975.

4. Groups I - VI are different methods. These inventions are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

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Species Election

Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

5. In any one of the Group I-VI is elected, applicant is required to elect a specific method for improving a patient's immune response wherein : (i) a specific pharmaceutical is selected from the group recited in claim 36; (ii) a specific cell is selected from the group recited in claim 45 ; (iii) a specific immunosuppressant is selected from the group recited in claim 49.

These species are distinct because the methods for improving a patient's immune response wherein (i) a specific pharmaceutical is selected from the group recited in claim 36; (ii) a specific cell is selected from the group recited in claim 45 ; (iii) a specific immunosuppressant is selected from the group recited in claim 49 differ with respect to the use of specific pharmaceutical, specific cell and specific immunosuppressant ; thus each specific method employing a specific pharmaceutical, specific cell and specific immunosuppressant represents patentably distinct subject matter. Furthermore, the examination of (i) a specific pharmaceutical is selected from the group recited in claim 36; (ii) a specific cell is selected from the group recited in claim 45 ; (iii) a specific immunosuppressant is selected from the group recited in claim 49 in the method for improving a patient's immune response would require different searches in the scientific literature.

In addition, if applicant elects Group III or VI, then applicant is required to elect from the following as well:

6. If Group III or VI is elected, applicant is further required to elect: (i) a specific method for improving a patient's immune response wherein specific pharmaceutical is, for example, selected from the Groups recited in Claims 29 or 30; (ii) a specific mode of administering a formulation, such as ones recited in claim 28.

These species are distinct because the methods for improving a patient's immune response wherein specific pharmaceutical is, for example, selected from the Groups recited in Claims 29 or 30; (ii) a specific mode of administering a formulation, such as ones recited in claim 28 differ with respect to the use of specific pharmaceutical and mode of administering a formulation; thus each specific method employing a specific pharmaceutical and specific mode of administering represents patentably distinct subject matter. Furthermore, the examination of specific pharmaceutical such as ones recited in the Claims 29 or 30; in the method for improving a patient's immune response would require different searches in the scientific literature.

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Applicant is advised that a response to this requirement **must include an identification of the species that is elected** consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.


Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
July 21, 2003


PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
RE: 09/977,479
7/24/03